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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/747,926	12/29/2003	Stephen Eliot Zweig		7076

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STEPHEN E. ZWEIG
224 VISTA DE SIERRA
LOS GATOS, CA 95030

EXAMINER	
LIN, JERRY	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 08/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/747,926	ZWEIG, STEPHEN ELIOT	
	Examiner	Art Unit	
	Jerry Lin	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *14-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 5-13* is/are rejected.

7)☒ Claim(s) *4* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2 pages (12/29/03)*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. An examination of this application reveals that applicant is unfamiliar with patent prosecution procedure. While an inventor may prosecute the application, lack of skill in this field usually acts as a liability in affording the maximum protection for the invention disclosed. Applicant is advised to secure the services of a registered patent attorney or agent to prosecute the application, since the value of a patent is largely dependent upon skilled preparation and prosecution. The Office cannot aid in selecting an attorney or agent.

A listing of registered patent attorneys and agents is available on the USPTO Internet web site http://www.uspto.gov in the Site Index under "Attorney and Agent Roster." Applicants may also obtain a list of registered patent attorneys and agents located in their area by writing to the Mail Stop OED, Director of the U. S. Patent and Trademark Office, PO Box 1450, Alexandria, VA 22313-1450

Election/Restrictions

2. Applicant's election of Group I, claims 1-13 in the reply filed on June 8, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Objections

3. Claim 4 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 4 includes a limitation of a therapeutic protein drug, however the instant claims are not drawn to a therapeutic protein drug, but a time-temperature indicator device. Thus the claim does not further limit its parent claim 1.

Claim Rejections - 35 USC § 112, 2nd Paragraph

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-13 are rejected as failing to define the invention in the manner required by 35 U.S.C. 112, second paragraph.

The claim(s) are narrative in form and replete with indefinite and functional or operational language. The structure which goes to make up the device must be clearly and positively specified. The structure must be organized and correlated in such a manner as to present a complete operative device. The claim(s) must be in one sentence form only. Note the format of the claims in the patent(s) cited.

6. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the components of the

time-temperature indicator device. The instant claims are drawn to a time-temperature indicator device. Although the specification on pages 15-18 does disclose the components of a time-temperature indicator device, the instant claims do not disclose what components are required for the time-temperature device. Furthermore, since there are no elements disclosed, the claims are also incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01.

7. Regarding claims 1 and 7, the instant claims recites a list of activities from line 5 and line 7 respectively to the end of the instant claims. It is unclear who is performing these activities. One interpretation is that a practitioner performs the activities. Another interpretation is that the device itself performs the activities. For purposes of this examination, the former interpretation will be used.

8. Also regarding claims 1 and 7, it is unclear who is doing the selecting or how the selection occurs in line 4. One interpretation is that a practitioner performs the selection. Another interpretation is that the device itself performs the selection. For purposes of this examination, the former interpretation will be used.

9. Regarding claims 1, 5, and 7, it is unclear where the preamble ends and where the limitations begin. Applicant is advised to incorporate transitional language to clarify. See MPEP §2111.03.

10. Regarding claim 5, the instant claim is drawn to a device, however the limitations listed in the claim are method steps of how the device operates. It is unclear what components these limitations are intended to describe.

11. Claim 5 recites the limitation "the relevant temperature" in line 4. There is insufficient antecedent basis for this limitation in the claim. This term is not mentioned previously in the instant claim, and it is not clear to what it is referring. It also is unclear when or under what conditions does the temperature become irrelevant.

12. Claim 5 recites the limitation "that period's length of time" in line 7. There is insufficient antecedent basis for this limitation in the claim. This term is not mentioned previously in the instant claim, and it is not clear to what it is referring.

13. Regarding claim 5, the word "means" is preceded by the word(s) "computational" and "temperature" in an attempt to use a "means" clause to recite a claim element as a means for performing a specified function. However, since no function is specified by the word(s) preceding "means," it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967).

14. The terms "small enough" or "often enough" in claim 5 are a relative terms which renders the claim indefinite. The terms "small enough" or "often enough" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 112, 1st Paragraph

15. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

16. Claims 6 and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention.

Instant claims 6 and 13 are drawn to the claimed device additionally monitoring motion, vibration, light or turbidity. The specification on page 18 indicates that these additional parameters may be included with the claimed device. However, neither the specification nor the claims teach what elements are required with the device in order to measure these additional parameters. Although there are different types of sensing devices known in the art, one of skill in the art must still incorporate these sensing devices with the claimed invention. Given that it is unclear what elements are required for the claimed device, and that one of skill in the art must still incorporate these sensing devices for the additional parameters with the claimed invention, one of skill in the art must perform undue experimentation to make the invention. Thus without further guidance from the specification, one of skill in the art cannot make the invention without undue experimentation.

Claim Rejections - 35 USC § 102

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

18. Claims 1-3, 5, 7-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Karr et al. (US 4,277,974).

The instant claims are drawn to a time-indicator device. Although the claims indicate that the device is used for monitoring a therapeutic protein drug, such intended use is not given patentable weight.

Regarding claims 1 and 7, Karr et al. teaches an electronic time temperature indicator device with a parameter (abstract). In claims 1 and 7, the limitations listed from line 4 and line 6, respectively, to the end of the instant claims are all activities that occur outside the device. Thus these activities do not describe the device itself. Since the claim is drawn to a device and the activities do not describe the device, the activities are not given any patentable weight. Furthermore, in lines 1-4 and lines 1-6 respectively, the instant claim recites an intended use. This recitation is also not given patentable weight. Thus the instant claim is drawn to a time-temperature device with one time-temperature indication parameter as taught by Karr et al.

Regarding claim 2, 3, and 8, Karr et al. disclose wherein their device is electronic (abstract) and is chemical (consumption of the electrode is a chemical process) (abstract) and has a visual display (abstract).

Regarding claim 5, Karr et al. disclose sampling temperature continuously (column 2, lines 5-31); computing a function to determine the impact of time and temperature (column 5, line 11- column 6, line 40); comparing the result of the function

to a reference value (column 5, line 11- column 6, line 40); then generating a output for the fitness of the drug (column 4, lines 15-25).

Regarding claim 9, Karr et al. disclose wherein the device is programmed with time-temperature indication parameters (column 5, lines 11-40).

Regarding claim 10, Karr et al. teach having an integrated circuit chip (microprocessor) and power from a battery (column 3, lines 1-65).

Regarding claim 11, Karr et al. teach where the device indicates the percentage of remaining lifetime (for example, if rejected the remaining lifetime is zero) (column 4, liens 14-20).

Regarding claim 12, Karr et al. teach wherein the device is attached to a dispensing device (column 3, lines 52-68).

Double Patenting

19. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

20. Claims 1-13 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1-33 of U.S. Patent No. 6,950,028. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of US Patent No. 6,950,028 are also drawn to electronic time-temperature devices. Given the interpretation of the instant claims, instant claims 1-13 are also drawn to electronic time-temperature devices. Thus the conflicting claims are drawn to the same invention.

21. Claims 1-13 are provisionally rejected on the ground of nonstatutory double patenting over claims 1-25 of copending Application No. 10/824709. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: Application No. 10/824709 are drawn to electronic time-temperature devices. Given the interpretation of the instant claims, instant claims 1-13 are also drawn to electronic time-temperature devices. Thus the conflicting claims are drawn to the same invention.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Lin whose telephone number is (571) 272-2561. The examiner can normally be reached on 10:00am-6:30pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Representatives are available to answer your questions daily from 6 am to midnight (EST). When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within

5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center at (800) 786-9199.

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

JL